

TAB 1

K093800

Revised 2

510(k) Summary

As required by the Safe Medical Device Act of 1990, and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Robinson MedSurg QuickScrew Racks

Date Prepared: December 1, 2009

JUN 13 2010

A. Submitter's Name

Robinson MedSurg, LLC
7430 E. Park Meadows Drive, Suite 300
Lone Tree, CO 80124

Establishment Registration Number: #3006119027

B. Company Contact

Peggy Henline
Operations Manager
T. 303-706-1100
F. 303-662-8484
phenline@robinsonmedsurg.com

C. Device Name

Trade Name: Robinson MedSurg QuickScrew Rack RCK24-143
Common Name: Sterilization Rack
Classification: Sterilization Wrap Containers, Trays, Cassettes and Other Accessories
Regulatory Class: II
Product Code: KCT
Classification Number: 21 CFR §880.6850

D. Predicate Devices

The subject Robinson MedSurg QuickScrew Rack RCK24-143 is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution: Smith and Nephew Instrument Tray cleared under K073551, Smith and Nephew Instrument Trays cleared under K090562, and the ContainMed Versipod Instrument Trays cleared under K071783.

E. Description of Device

DEVICE DESCRIPTION: The Robinson MedSurg QuickScrew Rack RCK24-143 is an instrument rack for organizing, holding, and protecting reusable surgical instruments during transportation, storage, and sterilization. It is designed for adequate exposure of the trays' contents to sterilant during the sterilization process.

The Rack is made of anodized aluminum with polyetherimide tube holders for the instruments and to allow for air and sterilant to flow through and around the rack.

F. Intended Use

The Robinson MedSurg QuickScrew Rack RCK24-143 is intended to organize, hold, and protect the QuickScrew screwdrivers for transport, storage, sterilization, and use during surgery. The subject instrument racks are suitable for use in prevacuum steam. The subject instrument trays are not intended to maintain sterility; they are intended to be used in conjunction with a validated FDA cleared sterilization wrap in order to maintain sterility of the enclosed devices.

Validated Sterilization Parameters:

Method	Temperature	Exposure Time	Drying Time
Prevacuum Steam Autoclave	270°F (132°C)	4 minutes	60 minutes

G. Comparison of Technological Characteristics

The subject Robinson MedSurg QuickScrew Racks RCK24-143 have the same fundamental technological characteristics as the predicate devices. The subject racks are substantially equivalent in design, materials, and intended use to the predicate devices. There are no significant differences between the proposed and predicate devices that raise new questions of safety or efficacy and is, therefore, substantially equivalent to the predicate devices.

H. Summary of Performance Data

Performance testing was conducted according to AAMI ST77:2006 *Containment Devices for reusable medical device sterilization*. The rack conforms to this standard and performed as intended.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Mr. Randolph C. Robinson
President
Robinson Medsurg LLC
7430 East Park Meadows Drive, Suite 300
Lone Tree, Colorado 80124

JUN 13 2010

Re: K093800

Trade/Device Name: Robinson MedSurg QuickScrew Rack Model RCK 24-143
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: May 16, 2010
Received: May 19, 2010

Dear Mr. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

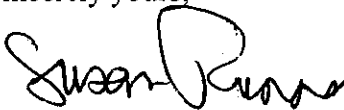
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


f

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement510(k) Number: K093800

Device Name: Robinson MedSurg QuickScrew Rack Model RCK 24-143

Indications for Use:

The Robinson MedSurg QuickScrew Rack RCK24-143 is intended to organize, hold, and protect the QuickScrew screwdrivers for transport, storage, sterilization, and use during surgery. The subject instrument racks are suitable for use in prevacuum steam. The subject instrument trays are not intended to maintain sterility; they are intended to be used in conjunction with a validated FDA cleared sterilization wrap in order to maintain sterility of the enclosed devices.

Validated Sterilization Parameters:

Method	Temperature	Exposure Time	Drying Time
Prevacuum Steam Autoclave	270°F (132°C)	4 minutes	60 minutes

Prescription Use
(Part 21 CFR 801 Subpart D)

and/or

Over-The-Counter Use XX
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Page 1 of 1

510(k) Number: K093800